REMARKS

The above Amendments and these Remarks are in reply to the Office Action mailed 6 June 2008.

Claims 1-5, 7-30, 36, 45-109, 118, 137, 139 and 140 were pending in the Application prior to the outstanding Office Action; with claims 7, 12-30, 36, 45-109, 118 and 137 being withdrawn. In the Office Action, the Examiner rejected claims 1-5, 8-11, 139 and 140. The present Response amends claims 1 and 4, leaving for the Examiner's present consideration claims 1-5, 7-30, 36, 45-109, 118, 137, 139 and 140. Reconsideration of the rejections is requested.

I. CLAIM OBJECTIONS

The Examiner objected to claims 1 and 4 on the ground that the meaning of "CRF" is unclear to the Examiner. The Examiner suggested changing "CRF" to "case report form".

This has been done.

II. REJECTIONS UNDER 35 USC 112

The Examiner rejected all the claims under 35 USC 112, second paragraph, as being indefinite. Specifically, the Examiner considers it unclear whether a specified test and a specified CRF are both required or if they are in the alternative only.

Applicants respectfully submit that there is nothing unclear about the claim language.

Claim 1 recites, among other things:

> "wherein the post-enrollment workflow tasks include at least one element of the group consisting of a post-enrollment instruction to have a specified test performed on the patient, and a post-enrollment instruction to have a specified case report form completed for the patient."

The claim therefore calls for the "post-enrollment workflow tasks" to include at least one element of a Markush group. The recited Markush group has two elements:

A. a post-enrollment instruction to have a specified test performed on the patient, and

B. a post-enrollment instruction to have a specified case report form completed for the patient

Since claim 1 calls for the "post-enrollment workflow tasks" to include "at least one" of these, only one of these is required to satisfy the language of the claim. Applicants respectfully do not see anything unclear about this language.

The Examiner also points to claim 4, which depends from claim 1, and adds:

"wherein said first plurality of workflow tasks includes the post-enrollment instruction to have a specified case report form completed for the patient."

This is element B of the Markush group.

Thus whereas claim 1 calls for at least one of the group consisting of A and B, claim 4 adds the limitation calling for B. Applicants do not see any interpretation for this language other than that in order to satisfy the language of the claim, at least element B is required. Element A may be present as well, but it is not required by claim 4.

The Examiner also points to claim 5, which depends from claim 4, and adds:

"wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient."

This is element A of the Markush group.

Thus whereas the language of claim 4 requires element B and does not require element A, the language of element 5 adds a requirement that the post-enrollment workflow tasks also include element B. Applicants see no other interpretation of this claim structure than that the language of claim 5 requires that the post-enrollment workflow tasks include both elements A and B of the Markush group.

The Examiner also points to claim 140, which depends from claim 1 and adds:

"wherein said post-enrollment workflow tasks include the post-enrollment instruction to have a specified test performed on the patient."

This is element A of the Markush group.

Thus whereas claim 1 calls for at least one of the group consisting of A and B, claim 140 adds the limitation calling for A. Applicants do not see any other interpretation for this language other than that in order to satisfy the language of the claim, at least element A is required. Element B may be present as well, but it is not required by claim 140.

In summary:

Claim 1 calls for the "post-enrollment workflow tasks" to include either A or B or both.

Claim 4 calls for it to include at least B

Claim 5 calls for it to include both A and B

Claim 140 calls for it to include at least A.

Accordingly, Applicants respectfully submit that there is nothing unclear about the claim language. If Applicants are missing something, and the Examiner believes that the above intent is not properly captured by the language presently recited in the claims, then Applicants respectfully request that the Examiner telephone the undersigned to explain the problem more specifically. Applicants would welcome the opportunity to make any amendments necessary to clarify their claims. Otherwise, it is respectfully submitted that the rejection under 35 USC 112 should be withdrawn.

III. ART REJECTIONS

The Examiner rejected claims 1, 2, 4, 10, 11 and 139 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Gillings. Dependent claim 3 was rejected over a combination of Colon, Gillings and Cimino, and dependent claims 5 and 140 were rejected over a combination of Colon, Gillings and Coli. Claims 8 and 9 were rejected over a combination of Colon, Gillings and McAlindon.

A. Independent Claim 1

The Examiner takes the position that Colon teaches all the elements of claim 1 except that the "post-enrollment workflow tasks" include either A or B above. To remedy this deficiency, the Examiner cites Gillings as teaching B, that the post-enrollment workflow tasks include "a post-enrollment instruction to have a specified case report form completed for the patient."

Specifically, the Examiner points to col. 5, lines 12-30 of Gillings as teaching "a post-enrollment instruction to have a specified case report form completed for the patient."

But that section of Gillings teaches only that his data management system is "used" to "manage" CRFs, to "process data contained" in CRFs, and to analyze the data collected. His database can even contain the CRFs themselves. But there is no *instruction* identified by his database to have a specified CRF completed.

An "instruction" is "a direction calling for compliance: order". Merriam-Webster Online Dictionary, retrieved November 25, 2008, from http://www.merriam-

webster.com/dictionary/instruction, definition 1 (copy attached hereto for the convenience of the Examiner.)

There is no "direction" in Gillings' database "calling for compliance" to "have a specified case report form completed". Merely storing a copy of the form in the database is not the same as storing in the database an "instruction" to have the form completed.

In embodiments in Applicants' specification, for example at p.23, lines 12-22, the database contains the workflow of the protocol in the form of patient visits, management tasks to take place during a visit, and transitions from one visit to another. The Visit class in the database includes a "slot" for patient management "tasks", which can include an instruction to have a specified CRF completed for the patient. "In other words, a clinical trial protocol prepared using this clinical trial protocol meta-model can include instructions to clinical personnel not only for patient management tasks (such as administer certain medication or take certain tests), but also data management tasks (such as to complete certain CRFs)."

Gillings' database does not include any instructions to complete a CRF. It contains CRFs, which is to be expected of a typical electronic document management system, but does not contain any instructions for the clinician to have one completed.

Accordingly, neither reference of the Examiner's combination teaches an element of claim 1, and therefore the combination does not state a *prima facie* case of obviousness. Applicants therefore respectfully submit that claim 1 should be patentable.

B. Dependent Claims 2, 4, 10, 11 and 139

The Examiner also rejected dependent claims 2, 4, 10, 11 and 139 over the combination of Colon and Gillings.

These claims all depend ultimately from independent claim 1 and therefore are believed to be patentable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each add their own limitations which, it is submitted, render them patentable in their own right.

Claim 4, for example, calls for the "first plurality of workflow tasks" identified by the machine readable database of claim 1 to include specifically the post-enrollment instruction, mentioned in claim 1, to have a specified CRF completed for the patient. As already mentioned

with respect to claim 1, neither Colon nor Gillings indicate that an instruction such as this be included in their database.

Claims 10 and 11, for example, each call for the plurality of workflow tasks identified by the database to include "an instruction to enroll a patient into a clinical trial". The Examiner points to Colon, col.5, lines 25-35 as teaching this feature, but that excerpt describes only an eligibility/randomization table containing a row for each subject already enrolled in a study. There does not appear to be any instruction ("direction calling for compliance: order") in Colon's database, to perform the process of enrolling the patient.

This can be seen further in Fig. 5 and col. 6, lines 39-55 of Colon. Here Colon says that his application program tests to see if the patient meets the eligibility parameters for the study, and if so, then the patient is "randomized" (e.g. assigned randomly to one of the study strategies). Then the application program sends out a suggested drug prescription.

The program seems to skip over any step of instructing that the patient actually be enrolled, which is what is called for in Applicants' claims 10 and 11. Rather, this step appears to be left to the clinician to figure out herself.

Knowing exactly when to perform the specific process of "enrolling" the patient is not necessarily a trivial detail. Typically the patient first must be fully informed of the risks of enrollment and must sign a prescribed consent form before enrollment. Often some of the tests required to determine eligibility can be performed prior to informed consent, and often some the tests must be performed after informed consent and before enrollment. See, for example, Applicants' Fig. 4 and page 27, lines 3-21 of Applicants' specification. It can be seen that having an instruction to go ahead and enroll the patient, can be an important benefit.

Colon does not teach that his database include "an instruction to enroll a patient into a clinical trial", as called for in Applicants' claims 10 and 11. Accordingly, claims 10 and 11 should be allowable for this reason as well.

Dependent claims 2 and 139 should be allowable both because of their dependency from independent claim 1, and also because of the limitations they each add.

Accordingly, dependent claims 2, 4, 10-11 and 139 should all be patentable.

C. Dependent Claim 3

The Examiner rejected claim 3 as being unpatentable over Colon in view of Gillings and further in view of Cimino.

Claim 3 depends from independent claim 1 and therefore is believed to be patentable for at least the reasons set forth above with respect to independent claim 1. In addition, as already pointed out in Applicants' Response E filed December 6, 2006, claim 3 adds its own limitations which, it is submitted, render the claim patentable in its own right.

Claim 3 calls for, among other things:

> wherein said database identifies a term by reference to a controlled medical terminology database.

Thus the claim calls for the same database that identifies patient eligibility criteria for a clinical trial protocol also to identify post-enrollment workflow tasks to be performed during the operation of the clinical trial. By using a CMT in the clinical trial protocol database, greater unification can be achieved among the various stages of a clinical trial that were previously seen as widely disparate.

The Examiner cites pp. 154 and 162 of Cimino as teaching that "controlled medical terminologies (CMTs) are at the heart of most medical systems." But Cimino is speaking of a more common use of CMTs, to support "distributed cognition in patient care." Cimino, p. 161. As mentioned in Applicants' specification at p. 17, lines 7-8, CMTs were not originally intended for use in the field of clinical trial protocols. Cimino is no exception to this general understanding.

Cimino does not appear even to mention clinical trials, much less suggest that CMTs can be used in a database that identifies widely disparate features of a clinical trial protocol. The Examiner's citation to Cimino p. 161 as motivating such a combination is to no avail because there Cimino was speaking of patient care applications, not clinical trial protocols.

Accordingly, claim 3 is believed to be patentable in its own right.

D. Dependent Claims 5 and 140

The Examiner rejected claims 5 and 140 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Gillings and further in view of Coli.

These claims each depend ultimately from independent claim 1 and therefore are believed to be patentable for at least the reasons set forth above with respect to independent claim 1.

Claim 5 also depends from dependent claim 4, and therefore should be patentable also for the reasons set forth above with respect to dependent claim 4. In addition, claims 5 and 140 each add their own limitations which, it is submitted, render the claim patentable in its own right.

Specifically, claims 5 and 140 each call for, among other things:

> wherein said post-enrollment workflow tasks further include the post-enrollment instruction to have a specified test performed on the patient.

The Examiner cites Coli, col. 4, line 62 - col. 5, line 31 as teaching this feature. However, Applicants are unsure of which element of the cited text the Examiner believes constitutes an "instruction to have a specified test performed". In fact, the step (1) recited at col. 5, lines 25-26, "receive a user request for a laboratory test", implies that it is the user (e.g. the clinician), not any workflow task in a database, that provides the instruction to have the test performed.

The Examiner may be considering step (7) recited at col. 5, lines 19-22, "cause a message that comprises the patient ID, patient's insurance carrier, diagnosis, and test ID to be communicated to the lab that is to conduct the test", as satisfying Applicants' claimed "instruction to have a specified test performed." But this instruction is not embodied in a "workflow task" in a database, as called for in the claim.

Moreover, none of the steps in the cited section of Coli constitute "post-enrollment" workflow tasks. Parent claim 1 calls for the post-enrollment workflow tasks to be "for said first clinical trial protocol." Coli's system is for use by treating health care practitioners, labs, insurers, etc., during normal patient care, not for use with a clinical trial protocol. And given all the science-based and FDA-mandated rigor surrounding clinical trials, it is uncertain that Coli's system could be used for that purpose even if desired.

Accordingly, Coli fails to teach a database identifying a workflow task for a clinical trial protocol, as called for in Applicants' claim. Nor does it teach that such a database identify a post-enrollment task for such a protocol, and certainly not a database that identifies a post-enrollment workflow task that includes a post-enrollment instruction to have a specified test performed on a patient. None of the references in the Examiner's combination therefore teach the limitations of claims 5 and 140, and claims 5 and 140 therefore should be patentable.

E. Rejection of Claims 8 and 9 under 35 U.S.C. §103(a)

The Examiner rejected claims 8 and 9 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Gillings and further in view of McAlindon.

Claims 8 and 9 both depend ultimately from independent claim 1 and therefore are believed to be patentable for at least the reasons set forth above with respect to independent claim 1. In addition, claims 8 and 9 each add their own limitations which, it is submitted, render the claim patentable in its own right.

Claim 8, for example, adds a limitation that the workflow tasks identified by the machine readable database include "an instruction to obtain specified patient medical information before an instruction to obtain informed consent." Claim 9 depends from claim 8 and adds a limitation that the workflow tasks identified by the machine readable database further include "a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent."

The Examiner cites col. 4, lines 37-45 and col. 5, lines 5-25 of McAlindon as teaching this feature. However, nothing in these sections of McAlindon teaches such an instruction in a workflow task identified by a database, as called for in Applicants' claim.

Accordingly, Applicants respectfully submit that claims 8 and 9 should be patentable, both by reason of their ultimate dependency from claim 1, and by reason of the additional limitations in these claims.

Applicants also note that McAlindon bears a filing date of April 28, 2000, which is subsequent to the date already established in the present proceedings for conception of the present invention. Should the Examiner persist in relying on any teaching in McAlindon under 35 USC 102(e), therefore, it would be necessary for the Examiner to also find support for that teaching in McAlindon's provisional application, which was filed on April 29, 1999. Otherwise, McAlindon would not constitute prior art. A copy of McAlindon's provisional application is being submitted with an IDS concurrently herewith. Applicants have looked for such a teaching in the provisional application, but respectfully do not find it.

IV. OTHER MATTERS AND CONCLUSION

The references cited by the Examiner but not relied upon have been reviewed, but are not believed to render the claims unpatentable, either singly or in combination.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any fee(s) that may be required in connection with this Response, or to credit any overpayment, to Deposit Account No. 50-0869 (FSTK 1000-0).

Respectfully submitted,

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